Complete Summary

GUIDELINE TITLE

(1) Part I. Guidelines for the management of severe traumatic brain injury. In: Management and prognosis of severe traumatic brain injury. (2) Update notice. Guidelines for the management of severe traumatic brain injury: cerebral perfusion pressure.

BIBLIOGRAPHIC SOURCE(S)

Brain Trauma Foundation, Inc, American Association of Neurological Surgeons, Congress of Neurological Surgeons, Joint Section on Neurotrauma and Critical Care. Guidelines for the management of severe traumatic brain injury: cerebral perfusion pressure. New York (NY): Brain Trauma Foundation, Inc.; 2003 Mar 14. 14 p. [47 references]

Brain Trauma Foundation, Inc., American Association of Neurological Surgeons. Part 1: guidelines for the management of severe traumatic brain injury. New York (NY): Brain Trauma Foundation, Inc.; 2000. 165 p. [299 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Severe traumatic brain injury

GUIDELINE CATEGORY

Diagnosis Management Treatment

CLINICAL SPECIALTY

Emergency Medicine Neurological Surgery Neurology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To address key issues relating to the management of severe traumatic brain injury in adult patients with a Glasgow Coma Scale (GCS) score ranging from 3 to 8
- To state the current scientific basis for clinical practice

TARGET POPULATION

Patients with severe traumatic brain injury (Glasgow Coma Scale [GCS] score of 3 to 8)

INTERVENTIONS AND PRACTICES CONSIDERED

- Trauma system development and organization (responsive system of care for patients with neurotrauma, including prehospital management and triage, direct trauma center transport, maintenance of appropriate call schedules, review of trauma care records for quality improvement, and participation in trauma education programs)
- 2. Initial management (use of sedation and neuromuscular blockade, management of hypotension and hypoxia, use of mannitol, and use of hyperventilation)
- 3. Resuscitation of blood pressure and oxygenation, including use of endotracheal intubation and resuscitation fluids (e.g., Ringer's lactate, normal or hypertonic saline)
- 4. Computed tomography scan
- 5. Intracranial pressure: monitoring, treatment threshold, technology awareness
- 6. Clinical manipulation and enhancement of cerebral infusion pressure
- 7. Use of hyperventilation, with monitoring of jugular venous oxygen saturation (SjO₂), arterial jugular venous oxygen (AVdO₂) content difference, brain tissue oxygen monitoring, and cerebral blood flow monitoring to help identify cerebral ischemia
- 8. Use of mannitol to control raised intracranial pressure, with monitoring of serum osmolalities and maintenance of euvolemia
- 9. Use of barbiturates, such as pentobarbital, thiopental, and etomidate, to control intracranial pressure
- 10. Use of steroids, such as dexamethasone, triamcinolone, the 21-aminosteroid tirilazad, and methylprednisolone

Note: The use of steroids is not recommended in patients with severe head injury

11. Nutrition, using enteral or parenteral formulas

12. Use of anticonvulsant medication (e.g., phenytoin, carbamazepine, phenobarbital, valproate)

MAJOR OUTCOMES CONSIDERED

- Trauma-related morbidity and complications
- Mortality/survival rate
- Predictive value of hypotension and hypoxemia in outcome of brain injury
- Complications of intracranial pressure monitoring
- Accuracy of intracranial pressure monitoring devices
- Prognostic value of intracranial pressure measurement
- Incidence of post-traumatic seizures
- Nitrogen balance in patients with severe traumatic brain injury
- Direct and indirect costs of injury
- Level of disability/quality of life/level of recovery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Each author on the task force was assigned a topic and conducted a MEDLINE search, reviewed and graded clinical articles pertinent to the topic, then wrote a report.

Trauma Systems

A MEDLINE search from 1966 to 1998 identified articles with the key words "trauma systems" and "outcome". Twenty-three relevant manuscripts were used as a basis to assess the value of trauma systems. The guideline and options are derived from studies in trauma and neurotrauma care from a variety of peer-reviewed and other articles. Resources for Optimal Care of the Injured Patient: 1999, published by the American College of Surgeons Committee on Trauma, provides the basis for most recommendations regarding trauma hospital organization.

Initial Management

The process leading to this section differs from that of the others in that many of the conclusions have been derived from analyses outlined in other sections. In particular, material from the sections on hyperventilation, mannitol, and management of blood pressure and oxygenation were incorporated.

For the subject of sedation, a MEDLINE search from 1966 to 1998 was undertaken using the following key words: "head injury", "sedation", and "human subjects".

This produced 45 references that were reviewed for clinical relevance and outcome orientation. No article met these criteria.

For the subject of neuromuscular blockade, a MEDLINE search from 1966 to 1998 was undertaken using the following key words: "head injury" (and "neuromuscular blockade" or "pharmacologic paralysis" or "relaxation") and "human subjects". This produced 15 references that were reviewed for clinical relevance and outcome orientation. One article met these criteria.

Resuscitation of Blood Pressure and Oxygenation

A MEDLINE search from 1966 to 1998 was undertaken using the following key words: "head injury" (and "hypoxia" or "hypotension") and "human subject"; and "head injury" (and "field" or "pre-hospital" or "prehospital") and ("treatment" or "management" or "resuscitation"). The resultant references found to be directly relevant regarding outcome analysis and clinical orientation were individually reviewed for design, content, and relevance.

Indications for Intracranial Pressure Monitoring

A MEDLINE search from 1966 to 1998 was conducted using the following key terms: "head injury", "intracranial pressure", "intracranial hypertension", and "intracranial pressure monitoring". Only English language literature was reviewed. A search of "head injury and intracranial pressure" resulted in 753 articles that were cited on MEDLINE. "Head injury and intracranial hypertension" resulted in 146 articles cited. The authors narrowed the list down to papers that dealt specifically with clinical intracranial pressure monitoring, using the following terms: "head injury" and "intracranial pressure monitoring" (41 articles); "intracranial pressure" and "monitoring" and "indications" (27 articles.) The authors reviewed these articles and included the relevant ones, along with certain other articles identified from other sources. The authors chose papers that reported outcome and excluded those in which intracranial pressure was only incidentally relevant. No articles were excluded because of their conclusion alone.

Intracranial Pressure Treatment Threshold

A MEDLINE search back to 1966 was undertaken using the following query: "intracranial hypertension" or "ICP" or "intracranial pressure" and "head injury" and "treatment" or "management" or "resuscitation" and "threshold" or "level" and "human subject". This produced 146 references. Of these, 46 were found to be directly relevant to clinical orientation and the issue of relating intracranial pressure treatment threshold to outcome. The references were individually reviewed for design, content, and relevance.

Intracranial Pressure Monitoring Technology

A computerized literature search of MEDLINE from 1975 to January 1998 using the search words "monitor" and "intracranial pressure" found 4,290 articles, of which 1,000 articles were found to be pertinent to data in humans. Scientific publications on intracranial pressure monitoring devices used clinically and

reporting accuracy or complications were reviewed in depth. Case reports were excluded.

Cerebral Perfusion Pressure

A MEDLINE search for the headings of "cerebral perfusion pressure" and "brain injury" was performed for the period of 1970-2001; 267 references were generated and 45 dealt with clinical brain injury - 18 of these studies provided outcome data. One of the clinical studies prospectively randomized patients into groups treated at different cerebral perfusion pressure levels. Several of the studies were randomized, prospective trials of other therapies in conjunction with cerebral perfusion pressure management and involved sequential and prospective accumulation of physiological data.

Hyperventilation

The development of these guidelines began with an extensive review of all of the pertinent literature published in the past 25 years. Approximately 600 citations were acquired by computerized search of the National Library of Medicine using the following MeSH headings in combination with "head injuries": "ischemia", "jugular vein", "regional blood flow", "perfusion", and "hyperventilation". Abstracts from the publications were reviewed and relevant articles selected to develop the guideline. The authors focused on four areas: cerebral blood flow (30 articles reviewed); arterial jugular venous oxygen content differences (7 articles reviewed); jugular venous oxygen saturation analysis (6 articles reviewed); and hyperventilation (16 articles reviewed). All of these articles were cohort studies of more than 8 patients (Class II) and were published in peer reviewed journals except for 5--1 was a controlled, randomized prospective clinical trial (Class I) and 4 were case reports or reviews (Class III).

Use of Mannitol

"Mannitol" was listed 147 times associated with "brain trauma" in MEDLINE in a search of the past 25 years' literature, to January 1998. The majority of these citations were descriptive, discussing the use of mannitol, among other modalities, in head injury management or emergency trauma care. Only 4 of these citations were comparative studies or claimed an effect for mannitol alone on outcome. Forty-one citations were selected for review because they focused on the action of mannitol or its effect on outcome or critically reviewed its role in head trauma management.

Use of Barbiturates in the Control of Intracranial Hypertension

A second MEDLINE search from 1994 to January 1998 was undertaken using the following key terms: "barbiturates", "etomidate", "head injury", "ICP treatment", "pentobarbital", and "thiopental". This resulted in 406 citations. The abstracts of all citations were reviewed, yielding four clinically pertinent articles.

The Role of Steroids

A computer search was performed using MEDLINE for the period from 1966 to 1998 by using the key terms "head injury" and "steroids". A total of 60 documents were found. In addition, reference lists from the major clinical trials of steroid treatment in head injury and a recent meta-analysis of trials of steroid in head injury were examined. All clinical studies of head injury in humans were examined and reviewed in detail.

Nutrition

A MEDLINE search of the categories "brain injury" and "nutrition" was conducted for the years 1975 through 1997, and all publications in English were reviewed. Only articles discussing nutritional data in patients with head injury were referenced in the evidentiary tables in the guideline document and used as the primary source for conclusions. The methodology, results, and conclusions of each of these 29 references were studied.

Role of Antiseizure Prophylaxis Following Head Injury

A MEDLINE computer search using the key words "seizure" and "head injury" between 1966 and 1998 was performed. A total of 95 documents were found. In addition, the results of other National Institutes of Health-funded studies that have not been published and other clinical studies referred to in major review articles on post-traumatic seizures prophylaxis were reviewed. All clinical studies of seizure prophylaxis in head-injured patients were reviewed.

NUMBER OF SOURCE DOCUMENTS

Number of source documents used to construct evidence tables on the various topics related to management of severe traumatic brain injury:

Trauma systems: 18

Initial management: 17

Resuscitation of blood pressure and oxygenation: 26

Indications for intracranial pressure monitoring:

- Table 1 (Which patients are at high risk?): 18
- Table 2 (How does intracranial pressure monitoring influence patient management?): 16
- Table 3 (Does intracranial pressure monitoring improve outcome?): 13

Intracranial pressure threshold: 7

Intracranial pressure monitoring technology: 25 source documents on intracranial pressure monitoring device accuracy and stability. (There are additional source documents for optimal intracranial location of monitors, complications, and cost.)

Cerebral perfusion pressure: 17

Hyperventilation:

- Table I (Clinical cerebral blood flow, metabolic, and physiologic measurements following severe traumatic brain injury): 11
- Table 2 (Histologic evidence for ischemia following traumatic brain injury and evidence of widened arterial jugular venous oxygen content difference early after injury): 4
- Table 3 (Effects of hyperventilation on cerebral blood flow, arterial jugular venous oxygen content differences, jugular venous oxygen saturation analysis, brain tissue oxygenation, and clinical outcome): 14

Mannitol: 20

Barbiturates in the control of intracranial hypertension: 3

Role of steroids: 11

Nutrition: 35

Role of antiseizure prophylaxis following head injury: 8

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classification of Evidence

When assessing the value of therapies or interventions, the available data is classified into one of the following three categories according to the following criteria:

Class I evidence: Prospective, randomized, controlled trials (PRCT)--the gold standard of clinical trials. However, some may be poorly designed, lack sufficient patient numbers, or suffer from other methodological inadequacies.

Class II evidence: Clinical studies in which the data was collected prospectively, and retrospective analyses that were based on clearly reliable data. Types of studies so classified include: observational studies, cohort studies, prevalence studies, and case control studies.

Class III evidence: Most studies based on retrospectively collected data. Evidence used in this class indicates clinical series, databases or registries, case reviews, case reports, and expert opinion with some support from animal studies.

Technology assessment: The assessment of technology, such as intracranial pressure monitoring devices, does not lend itself to classification in the abovementioned format. Thus, for technology assessment the devices were evaluated in terms of their accuracy, reliability, therapeutic potential, and cost effectiveness.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Standards: Represent accepted principles of patient management that reflect a high degree of clinical certainty.

Guidelines: Represent a particular strategy or range of management strategies that reflect a moderate degree of clinical certainty.

Options: Are the remaining strategies for patient management for which there is unclear clinical certainty.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The task force authors actively involved representatives of national and international medical societies and individuals with demonstrated expertise and interest in the care of patients with severe traumatic brain injury.

The report was reviewed, critiqued, and revised by the entire task force and by representatives of various medical societies, individuals with expertise in head injury care, and members of the American Association of Neurological Surgeons Guidelines and Outcomes Committee. The document was critiqued in detail by a group of European neurosurgeons with expertise in neurotrauma.

In April 1995, the document was reviewed and approved by the American Association of Neurological Surgeons Guidelines and Outcomes Committee and the American Association of Neurological Surgeons Board of Directors. The guidelines were also reviewed by the American Academy of Neurology, the American College of Surgeons, the American College of Emergency Physicians, the American Society of Neuroradiology, the Society for Critical Care Medicine, the American Association of Neuroscience Nurses, and the American Academy of Physical Medicine and Rehabilitation. In 1998 the task force authors met to review the 1995 version of the guidelines and to update the scientific evidence and make other necessary changes. The term "Head Injury" as used in the original guidelines title was removed in favor of "Traumatic Brain Injury", which reflected a more prevalent usage in the literature reviews.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

"Degrees of Certainty" [Standards, Guideline, Options] and "Classification of Evidence" and the correlation between the two are defined at the end of the "Major Recommendations" field.

Trauma Systems

<u>Standards</u>: There are insufficient data to support a treatment standard for trauma systems.

<u>Guidelines</u>: All regions should have an organized trauma care system.

<u>Options</u>: As delineated in the American College of Surgeons Committee on Trauma Resources for Optimal Care of the Injured Patient: 1999, neurosurgeons should have an organized and responsive system of care for patients with neurotrauma. They should initiate neurotrauma care planning including prehospital management and triage, direct trauma center transport, maintain appropriate call schedules, review trauma care records for quality improvement, and participate in trauma education programs.

Trauma facilities treating patients with severe or moderate head injury must have a neurosurgery service, an in-house trauma surgeon, a neurosurgeon promptly available, and a continuously staffed and available operating room, intensive care unit, and laboratory with proper equipment for treating neurotrauma patients. A computed tomography scanner must be immediately available at all times.

In rural or occasionally weather-bound communities without a neurosurgeon, a surgeon should be trained to perform accurate neurological assessment and to initiate immediate neurotrauma care. Such a surgeon also should be trained to perform life-saving surgical treatment of an extracerebral hematoma in a deteriorating patient.

Initial Management

<u>Standards</u>: There are insufficient data to support a treatment standard for initial management.

<u>Guidelines</u>: There are insufficient data to support a treatment guideline for initial management.

Options: The first priority for the head-injured patient is complete and rapid physiologic resuscitation. No specific treatment should be directed at intracranial hypertension in the absence of signs of transtentorial herniation or progressive neurologic deterioration not attributable to extracranial explanations. When either signs of transtentorial herniation or progressive neurological deterioration not attributable to extracranial explanations are present, the physician should assume that intracranial hypertension is present and treat it aggressively. Hyperventilation should be rapidly established. The administration of mannitol is desirable but only under conditions of adequate volume resuscitation.

Sedation and neuromuscular blockade can be useful in optimizing transport of the head injury patient. However, both treatments interfere with the neurological examination. In the absence of outcome-based studies, the choice of sedative is left to the physician. Neuromuscular blockade should be employed when sedation alone proves inadequate and short-acting agents should be used when possible.

Resuscitation of Blood Pressure and Oxygenation

<u>Standards</u>: There are insufficient data to support a treatment standard for resuscitation of blood pressure and oxygenation.

<u>Guidelines</u>: Hypotension (systolic blood pressure [SBP] < 90 mm Hg) or hypoxia (apnea, cyanosis or an oxygen (O_2) saturation < 90% in the field or a PaO_2 < 60 mm Hg) must be monitored and scrupulously avoided, if possible, or corrected immediately in severe traumatic brain injury patients.

<u>Options</u>: The mean arterial blood pressure should be maintained above 90 mm Hg through the infusion of fluids throughout the patient 's course to attempt to maintain cerebral perfusion pressure (CPP) greater than 60 mm Hg. Patients with a Glasgow Coma Scale (GCS) score less than 9, who are unable to maintain their airway or who remain hypoxemic despite supplemental O_2 , require that their airway be secured, preferably by endotracheal intubation.

Indications for Intracranial Pressure Monitoring

<u>Standards</u>: There are insufficient data to support a treatment standard for intracranial pressure monitoring.

<u>Guidelines</u>: Intracranial pressure monitoring is appropriate in patients with severe head injury with an abnormal admission computed tomography scan. Severe head injury is defined as a Glasgow Coma Scale score of 3 to 8 after cardiopulmonary resuscitation. An abnormal computed tomography scan of the head is one that reveals hematomas, contusions, edema, or compressed basal cisterns.

Intracranial pressure monitoring is appropriate in patients with severe head injury with a normal computed tomography scan if two or more of the following features are noted at admission: age over 40 years, unilateral or bilateral motor posturing, systolic blood pressure <90 mm Hg.

Intracranial pressure monitoring is not routinely indicated in patients with mild or moderate head injury. However, a physician may choose to monitor intracranial pressure in certain conscious patients with traumatic mass lesions.

Intracranial Pressure Treatment Threshold

<u>Standards</u>: There are insufficient data to support a treatment standard for intracranial pressure treatment threshold.

<u>Guidelines</u>: Intracranial pressure (ICP) treatment should be initiated at an upper threshold of 20 to 25 mm Hg.

<u>Options</u>: Interpretation and treatment of ICP based on any threshold should be corroborated by frequent clinical examination and cerebral perfusion pressure (CPP) data.

Recommendations for Intracranial Pressure Monitoring Technology*

In the current state of technology the ventricular catheter connected to an external strain gauge is the most accurate, low-cost, and reliable method of monitoring ICP. It also allows therapeutic cerebrospinal fluid drainage. ICP transduction via fiberoptic or strain gauge devices placed in ventricular catheters provide similar benefits, but at a higher cost.

Parenchymal ICP monitoring with fiberoptic or strain gauge catheter tip transduction is similar to ventricular ICP monitoring but has the potential for measurement drift.

Subarachnoid, subdural, and epidural monitors (fluid coupled or pneumatic) are currently less accurate.

*Note: The assessment of ICP monitoring technology does not lend itself to classification of evidence as in other guideline sections, Thus the ICP devices were evaluated in terms of their accuracy, reliability, therapeutic potential, and cost effectiveness.

Guidelines for Cerebral Perfusion Pressure

<u>Standards</u>: There are insufficient data to support treatment standards for cerebral perfusion pressure.

<u>Guidelines</u>: Cerebral perfusion pressure (CPP) should be maintained at a minimum of 60 mm Hg. In the absence of cerebral ischemia, aggressive attempts to maintain cerebral perfusion pressure above 70 mm Hg with fluids and pressors should be avoided because of the risk of adult respiratory distress syndrome.

Hyperventilation

<u>Standards</u>: In the absence of increased ICP, chronic prolonged hyperventilation therapy ($PaCO_2 \le 25$ mm Hg) should be avoided after severe traumatic brain injury.

<u>Guidelines</u>: The use of prophylactic hyperventilation ($PaCO_2 \le 35$ mm Hg) therapy during the first 24 hours after severe traumatic brain injury should be avoided because it can compromise cerebral perfusion during a time when cerebral blood flow is reduced.

<u>Options</u>: Hyperventilation therapy may be necessary for brief periods when there is acute neurologic deterioration, or for longer periods if there is intracranial hypertension refractory to sedation, paralysis, cerebrospinal fluid drainage, and osmotic diuretics.

Jugular venous oxygen saturation (SjO₂), arterial jugular venous oxygen (AVdO₂) content differences, brain tissue oxygen monitoring, and cerebral blood flow monitoring may help to identify cerebral ischemia if hyperventilation, resulting in PaCO₂ values less than 30 mm Hg, is necessary.

The Use of Mannitol

<u>Standards</u>: There are insufficient data to support a treatment standard for the use of mannitol.

<u>Guidelines</u>: Mannitol is effective for control of raised ICP after severe head injury. Effective doses range from 0.25 g/kg body weight to 1 gm/kg body weight.

Options:

- The indications for the use of mannitol prior to ICP monitoring are signs of transtentorial herniation or progressive neurological deterioration not attributable to extracranial explanations. However, hypovolemia should be avoided by fluid replacement.
- Serum osmolarity should be kept below 320 mOsm because of concern for renal failure.
- Euvolemia should be maintained by adequate fluid replacement. A Foley catheter is essential in these patients.
- Intermittent boluses may be more effective than continuous infusion.

The Use of Barbiturates in the Control of Intracranial Hypertension

<u>Standards</u>: There are insufficient data to support a treatment standard for the use of barbiturates in the control of intracranial hypertension.

<u>Guideline</u>: High-dose barbiturate therapy may be considered in hemodynamically stable salvageable severe head injury patients with intracranial hypertension refractory to maximal medical and surgical ICP lowering therapy.

The Role of Steroids

<u>Standards</u>: The use of steroids is not recommended for improving outcome or reducing ICP in patients with severe head injury.

Guidelines: None

Options: None

Nutrition

<u>Standards</u>: There are insufficient data to support a treatment standard for nutrition.

<u>Guidelines</u>: Replace 140% of resting metabolism expenditure in non-paralyzed patients and 100% of resting metabolism expenditure in paralyzed patients using enteral or parenteral formulas containing at least 15% of calories as protein by the seventh day after injury.

<u>Options</u>: The preferable option is use of jejunal feeding by gastrojejunostomy due to ease of use and avoidance of gastric intolerance.

The Role of Antiseizure Prophylaxis Following Head Injury

<u>Standards</u>: Prophylactic use of phenytoin, carbamazepine, phenobarbital or valproate is not recommended for preventing late post-traumatic seizures.

Guidelines: None

Options: It is recommended as a treatment option that anticonvulsants may be used to prevent early post-traumatic seizures in patients at high risk for seizures following head injury. Phenytoin and carbamazepine have been demonstrated to be effective in preventing early post-traumatic seizures. However, the available evidence does not indicate that prevention of early post-traumatic seizures improves outcome following head injury.

Definitions:

Degrees of Certainty

Standards: Represent accepted principles of patient management that reflect a high degree of clinical certainty.

Guidelines: Represent a particular strategy or range of management strategies that reflect a moderate degree of clinical certainty.

Options: Are the remaining strategies for patient management for which there is unclear clinical certainty.

Classification of Evidence

Class I evidence: Prospective, randomized, controlled trials (PRCT)--the gold standard of clinical trials. However, some may be poorly designed, lack sufficient patient numbers, or suffer from other methodological inadequacies.

Class II evidence: Clinical studies in which the data was collected prospectively, and retrospective analyses that were based on clearly reliable data. Types of studies so classified include: observational studies, cohort studies, prevalence studies, and case control studies.

Class III evidence: Most studies based on retrospectively collected data. Evidence used in this class indicates clinical series, databases or registries, case reviews, case reports, and expert opinion with some support from animal studies.

Technology Assessment: The assessment of technology, such as ICP monitoring devices, does not lend itself to classification in the above-mentioned format. Thus, for technology assessment the devices were evaluated in terms of their accuracy, reliability, therapeutic potential, and cost effectiveness.

Correlation Between Evidence and Recommendation

Standards are generally based on Class I evidence. However, strong Class II evidence may form the basis for a standard, especially if the issue does not lend itself to testing in a randomized format. Conversely, weak or contradictory Class I evidence may not be able to support a standard.

Guidelines are usually based on Class II evidence or a preponderance of Class III evidence.

Options are usually based on Class III evidence and are clearly much less useful except for educational purposes and in guiding future studies.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Initial Resuscitation of the Severe Head Injury Patient
- Critical Pathway for the Treatment of Established Intracranial Hypertension

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVI DENCE SUPPORTING THE RECOMMENDATIONS

An evidentiary table appears at the end of each major section of the guideline document, which classifies each citation based on the quality of the evidence (Class I-III; see "Rating Scheme" above). The classification of evidence is correlated to the type of recommendation.

Standards are generally based on Class I evidence. However, strong Class II evidence may form the basis for a standard, especially if the issue does not lend

itself to testing in a randomized format. Conversely, weak or contradictory Class I evidence may not be able to support a standard.

Guidelines are usually based on Class II evidence or a preponderance of Class III evidence.

Options are usually based on Class III evidence and are clearly much less useful except for educational purposed and in guiding future studies.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Traumatic brain injury is a major cause of disability, death, and economic cost to society. Clinical and laboratory research has shown that all neurological damage does not occur at the moment of impact, but evolves over the ensuing hours and days. Therefore, developing better monitoring and treatment methods as well as the development of new pharmaceuticals will show great promise in improving the outcome for patients who have suffered a brain injury.

POTENTIAL HARMS

Not only do all treatment modalities for intracranial hypertension have serious potential complications, but many of them can directly interfere with resuscitation procedures (e.g., use of diuretics):

- Aggressive hyperventilation has the potential of exacerbating intracranial ischemia.
- Mannitol's osmotic diuresis may cause volume deficits, hypotension, and renal failure and may exacerbate intracranial pressure (ICP).
- ICP monitoring complications include infection, hemorrhage, malfunction, obstruction, and malposition. While these complications rarely produce long-term morbidity in patients, they can increase costs by requiring replacement of the monitor, and they can give inaccurate ICP readings.
- Barbiturates such as pentobarbital can produce hypotension and other cardiovascular complications.
- Anticonvulsants have been associated with adverse side effects including rashes, Stevens-Johnson syndrome, hematologic abnormalities, ataxia, and neurobehavioral side effects.
- A prospective randomized trial has demonstrated, however, that artificial attempts to maintain cerebral perfusion pressure above 70 mm Hg may be associated with an increased incidence of adult respiratory distress syndrome.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

• The information contained in the guideline reflects the current state of knowledge at the time of publication, February 2000. The information is designed to provide accurate and authoritative information in regard to the

subject matter covered. In view of the fact that there will be future developments in scientific information and technology, it is anticipated that there will be periodic review and updating of these guidelines. These guidelines are distributed with the understanding that the Brain Trauma Foundation, the American Association of Neurological Surgeons, and the other organizations that have collaborated in the development of these guidelines are not engaged in rendering professional medical services. If medical advice or assistance is required, the services of a competent physician should be sought. The recommendations contained in these guidelines may not be appropriate for use in all circumstances. The decision to adopt any particular recommendation contained in this guideline must be made by a treating physician in the light of all the facts and circumstances surrounding each particular case and on the basis of the available resources.

• These guidelines address key issues relating to the management of severe traumatic brain injury in adult patients with a Glasgow Coma Scale score of 3 to 8. They are by no means an exhaustive treatise on severe traumatic brain injury. Because of the enormous effort required to develop evidence-based guidelines, the task force authors selected topics that were deemed to have an impact on outcomes in patients with severe traumatic brain injury. Other important aspects of patient management that were not covered in the present effort will be considered for study in subsequent editions of this document. Examples of such topics include indications for neurological intervention, special consideration in pediatric head injury, the management of penetrating head injury, sedation and paralysis in the traumatic brain injury patient, and the economics of traumatic brain injury. The authors intend that these guidelines will be continually improved in response to new scientific evidence.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness Safety Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Brain Trauma Foundation, Inc, American Association of Neurological Surgeons, Congress of Neurological Surgeons, Joint Section on Neurotrauma and Critical Care. Guidelines for the management of severe traumatic brain injury: cerebral perfusion pressure. New York (NY): Brain Trauma Foundation, Inc.; 2003 Mar 14. 14 p. [47 references]

Brain Trauma Foundation, Inc., American Association of Neurological Surgeons. Part 1: guidelines for the management of severe traumatic brain injury. New York (NY): Brain Trauma Foundation, Inc.; 2000. 165 p. [299 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 (revised 2003)

GUI DELI NE DEVELOPER(S)

American Association of Neurological Surgeons - Medical Specialty Society Brain Trauma Foundation - Disease Specific Society

SOURCE(S) OF FUNDING

The Brain Trauma Foundation (BTF) financially supports and maintains these guidelines in a cooperative agreement with the American Association of Neurological Surgeons (AANS).

GUIDELINE COMMITTEE

Head Injury Guidelines Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: M. Ross Bullock, MD, PhD; Randall M. Chestnut, MD; Guy L. Clifton, MD; Jamshid Ghajar, MD, PhD; Donald W. Marion, MD; Raj K. Narayan, MD; David W. Newell, MD; Lawrence H. Pitts, MD; Michael J. Rosner, MD; Beverly C. Walters, MD; Jack E. Wilberger, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Brain</u> Trauma Foundation Web site.

Electronic copies of the revised chapter on cerebral perfusion pressure: Available in Portable Document Format from the Brain Trauma Foundation Web site.

Print copies: Available from the Brain Trauma Foundation, 523 East 72nd Street, New York, NY 10021, USA; Fax: 212-772-0357. An order form is also available on the Brain Trauma Foundation Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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